

## Centers for Medicare & Medicaid Services, HHS

## § 498.1

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AUTHORITY: Secs. 1102, 1128I and 1871 of the Social Security Act (42 U.S.C. 1302, 1320a-7j, and 1395hh).

SOURCE: 52 FR 22446, June 12, 1987, unless otherwise noted.

### Subpart A—General Provisions

#### § 498.1 Statutory basis.

(a) Section 1866(h) of the Act provides for a hearing and for judicial review of the hearing for any institution or agency dissatisfied with a determination that it is not a provider, or with any determination described in section 1866(b)(2) of the Act.

(b) Section 1866(b)(2) of the Act lists determinations that serve as a basis for termination of a provider agreement.

(c) Sections 1128 (a) and (b) of the Act provide for exclusion of certain individuals or entities because of conviction of crimes related to their participation in Medicare and section 1128(f) provides for hearing and judicial review for exclusions.

(d) Section 1156 of the Act establishes certain obligations for practitioners and providers of health care services, and provides sanctions and penalties for those that fail to meet those obligations.

(e)–(f) [Reserved]

(g) Section 1866(j) of the Act provides for a hearing and judicial review for any provider or supplier whose application for enrollment or reenrollment in Medicare is denied or whose billing privileges are revoked.

(h) Section 1128A(c)(2) of the Act provides that the Secretary may not collect a civil money penalty until the affected entity has had notice and opportunity for a hearing.

(i) Section 1819(h) of the Act—

(1) Provides that, for SNFs found to be out of compliance with the requirements for participation, specified remedies may be imposed instead of, or in

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addition to, termination of the facility's Medicare provider agreement; and

(2) Makes certain provisions of section 1128A of the Act applicable to civil money penalties imposed on SNFs.

(j) Section 1891(e) of the Act provides that, for home health agencies (HHAs) found to be out of compliance with the conditions of participation, specified remedies may be imposed instead of, or in addition to, termination of the HHA's Medicare provider agreement.

(k) Section 1891(f) of the Act—

(1) Requires the Secretary to develop a range of such remedies; and

(2) Makes certain provisions of section 1128A of the Act applicable to civil money penalties imposed on HHAs.

[52 FR 22446, June 12, 1987, as amended at 59 FR 56251, Nov. 10, 1994; 61 FR 32349, June 24, 1996; 73 FR 36462, June 27, 2008]

### § 498.2 Definitions.

As used in this part—

*Affected party* means a provider, prospective provider, supplier, prospective supplier, or practitioner that is affected by an initial determination or by any subsequent determination or decision issued under this part, and “party” means the affected party or CMS, as appropriate. For provider or supplier enrollment appeals, an affected party includes CMS or a CMS contractor.

*ALJ* stands for Administrative Law Judge.

*Departmental Appeals Board* or *Board* means a Board established in the Office of the Secretary to provide impartial review of disputed decisions made by the operating components of the Department.

*OIG* stands for the Department's Office of the Inspector General.

*Prospective provider* means any of the entities specified in the definition of provider under this section that seeks to be approved for coverage of its services by Medicare or to have any facility or organization determined to be a department of the provider or provider-based entity under § 413.65 of this chapter.

*Prospective supplier* means any of the listed entities specified in the definition of supplier in this section that seek to be approved for coverage of its services by Medicare.

*Provider* means either of the following:

(1) Any of the following entities that have in effect an agreement to participate in Medicare:

(i) Hospital.

(ii) Transplant center.

(iii) Critical access hospital (CAH).

(iv) Skilled nursing facility (SNF).

(v) Comprehensive outpatient rehabilitation facility (CORF).

(vi) Home health agency (HHA).

(vii) Hospice.

(viii) Religious nonmedical health care institution (RNHCI).

(2) Any of the following entities that have in effect an agreement to participate in Medicare but only to furnish outpatient physical therapy or outpatient speech pathology services.

(i) Clinic.

(ii) Rehabilitation agency.

(iii) Public health agency.

*Supplier* means any of the following entities that have in effect an agreement to participate in Medicare:

(1) An independent laboratory.

(2) Supplier of durable medical equipment prosthetics, orthotics, or supplies (DMEPOS).

(3) Ambulance service provider.

(4) Independent diagnostic testing facility.

(5) Physician or other practitioner such as physician assistant.

(6) Physical therapist in independent practice.

(7) Supplier of portable X-ray services.

(8) Rural health clinic (RHC).

(9) Federally qualified health center (FQHC).

(10) Ambulatory surgical center (ASC).

(11) An entity approved by CMS to furnish outpatient diabetes self-management training.

(12) End-stage renal disease (ESRD) treatment facility that is approved by CMS as meeting the conditions for coverage of its services.